United States Department of Agriculture

Agricultural Marketing Service

Fruit and Vegetable Programs

Processed Products Branch

File Code 151-B-4

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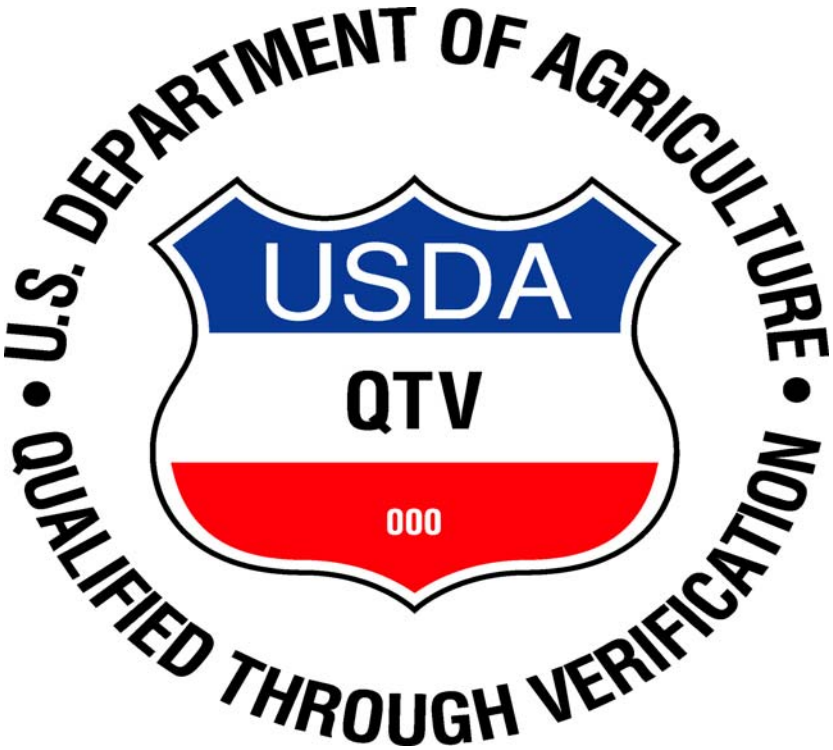
"Qualified Through Verification"(QTV) Program for the Fresh-Cut Produce Industry



AGRICULTURAL MARKETING SERVICE
QUALIFIED THROUGH VERIFICATION (QTV) PROGRAM MANUAL

EXECUTIVE SUMMARY

The Agricultural Marketing Service (AMS), Fruit and Vegetable Program's (FV) Qualified Through Verification (QTV) program is a voluntary, user-fee, audit-based inspection service for producers of fresh-cut fruits and vegetables. The program is designed to verify the suitability of a firm's Hazard Analysis Critical Control Points (HACCP) food safety system. QTV is a voluntary program. QTV empowers firms to apply science-based HACCP principles to identify food safety hazards in their food manufacturing processes and take steps to prevent, eliminate, or reduce the occurrence of the hazard to an acceptable level.

Under QTV, AMS reviews and assesses a firm's documented HACCP-based food safety QTV plan. After a plan is found to meet QTV program requirements, AMS uses on-site audits to determine the suitability of a firm's implementation of its plan. AMS auditors review records, observe and interview employees, conduct pre-operation sanitation inspections, and follow a specialized Systems Audit Checklist to verify that the company is following its QTV plan. Only companies that are able to meet existing good manufacturing and sanitation practices, source raw product from suppliers that comply with Good Agricultural Practices and Good Handling Practices, and demonstrate that they are following their QTV plan, including adherence to the required HACCP based techniques, are qualified to be in the program. QTV provides for reduced audit frequency when a facility has established and maintained a documented and verified food safety history. Firms in QTV meeting all program requirements may use the USDA QTV shield on packaging for products covered by the program.

This manual provides a description of the QTV program for current and potential applicants. AMS's program for the fresh-cut produce industry offers its clients value-added incentives. The requirements for participation in the QTV program include:

1. Orientation and Hazard Analysis Critical Control Point (HACCP) Training;
2. Successful Completion of an AMS Plant Survey;
3. Comprehensive Hazard Analysis;
4. Microbiological Testing Program;
5. Raw Produce Specifications with Suppliers' Successful Completion of Quarterly AMS "Good Agricultural Practices" and/or "Good Handling Practices" (GAP/GHP) Audits;
6. Implementation of a HACCP Program with Suitable Critical Control Points;
7. AMS Review of Company Plan and Prerequisite Programs;
8. Validation Audit;
9. Contract Agreement with AMS; and
10. Systems Audits for Verification by AMS

AMS can provide companies producing products that contain fresh-cut, minimally processed fruit or vegetable ingredients with the "Qualified through Verification" inspection service to

help them distribute safe, wholesome food products. Although the service focuses on continuous improvement in producing safe, wholesome food, this voluntary service can lead to substantial efficiencies in cost and personnel resources to the applicant.

Advertising and promotions must not misrepresent any USDA, AMS shield or suggest that only products bearing the shield are safe.

In addition to the criteria mentioned above, companies (herein referred to as applicants) interested in enrolling in this program must meet the following:

- Demonstrate a commitment by top management to QTV concepts and the scope of the program;

- Send personnel to approved HACCP training;

- Be "in production or service" at least four months of each year; and

Following the guidelines in this manual does not mitigate or affect in any way a food producer's responsibility to comply with the Federal Food, Drug, and Cosmetic Act or any other applicable Federal, State, or Local laws or regulations.

Address inquiries to:

Chief, Processed Products Branch
Fruit and Vegetable Programs, AMS
U.S. Department of Agriculture
1400 Independence Ave, SW
Room 0726 South Building
Washington, DC 20250-0001
Phone: (202) 720-4693
Fax: (202) 690-1527
or e-mailed to terry.bane@usda.gov.

Terry B. Bane
Branch Chief

Distribution: B
Agricultural: Washington

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PROGRAM SCOPE

QTV is a food safety program based on Hazard Analysis Critical Control Point (HACCP) principles, Good Manufacturing Practices (GMP's), AMS's "Good Agricultural Practices" and "Good Handling Practices" (GAP and GHP) Verification, effective sanitation programs, product recall planning, and microbiological testing. The Agency has found that QTV fosters a proactive approach by the production facility's management for identifying process deficiencies during production rather than after production is completed.

The QTV program is funded through user fees. Authority to charge fees for service is provided for under Title 7 Code of Federal Regulations (CFR) §52.5 1 (a). The QTV fee is charged for the time required by AMS personnel to review company QTV plans, travel to and from an audit site, perform the audit and associated administrative and management activities. All work conducted by AMS is charged on an hourly basis.

DEFINITIONS: Most of the following definitions[1] are the same as those established by the National Advisory Committee on Microbiological Criteria for Foods publication, "Hazard Analysis and Critical Control Point Principles and Application Guidelines," adopted August 14, 1997.

Audit Rating: The level achieved by an applicant based on their performance during a validation or systems audit. The audit rating is used to determine the facility rating.

Control Point: Any step in a process whereby biological, chemical, or physical hazards can be controlled.

Corrective Action: Procedures followed when a deviation occurs.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Deficiency: A deviation from the QTV Plan requirements or other condition(s) that has lead to an unsafe product or that brings the underlying commitment of the firm to the QTV program (e.g., falsified documents or interference with the audit) into question.

Critical Limit: A maximum and/or minimum value to which a biological, chemical or a physical parameter must be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.

Deviation: Failure to meet a critical limit.

[1] Exceptions to this are definitions specific to the QTV Program.

Facility Rating: The level a facility achieves based on the results, or audit rating, of a validation or systems audit. The facility rating is used to determine the frequency of the audits.

Good Agricultural Practices and Good Handling Practices (GAP and GHP) Verification: An audit verification program that helps the produce industry verify voluntary adherence to the Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." To inquire about GAP/GHP audits please contact USDA, AMS, Fruit and Vegetable Programs, Fresh Products Branch; 1400 Independence Avenue, SW; Room 1661, Stop 0240; Washington, D.C. 20250-0240; Phone: (202) 720-5870 or (202) 720-2482.

Good Manufacturing Practices: Food and Drug Administration regulations that describe the methods, equipment, facilities, and controls required for producing processed food (21 CFR 110).

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Hazard Analysis Critical Control Point (HACCP): A systematic approach to the identification, evaluation, and control of food safety hazards.

Hazard Analysis Critical Control Point (HACCP) **Plan:** The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP-Certified Training: Training for HACCP certification should include a minimum of 12 hours of instruction with a certificate issued upon completion. The agenda should include: an overview of HACCP, hazard analysis, preventative measures, critical control point determination, sanitation Standard Operating Procedures (SOP's), critical limits, monitoring procedures, corrective actions, record keeping, and how to develop a HACCP team and HACCP plan.

Major Deficiency: A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in an unsafe product.

Minor Deficiency: A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.

Notice of Unusual Occurrence and Corrective Action (NUOCA): Procedures that are followed by the applicant when an unusual occurrence not anticipated by the applicant's plan occurs. Examples of unusual occurrences include, but are not limited to: floods, hurricanes, tornados, earthquake, and rolling black outs.

Prerequisite Programs: Procedures, including Good Manufacturing Practices and Standard Operating Procedures (SOPs) that address operational conditions providing the foundation for the HACCP system.

Preventive or Control Measure(s): Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Process: One or more actions or operations to harvest, produce, manufacture, store, handle, distribute, or sell a product or a group of similar products.

QTV Plan: A description of a company's processes and procedures to assure the production of safe, wholesome product in accordance with HACCP, USDA and FDA criteria.

Serious Deficiency: A deviation from the QTV plan that has the potential to lead to and unsafe product and is highly objectionable (e.g., modification of critical limits without approval, records not available for inspection).

Sanitation Standard Operating Procedures (SSOP's): Written procedures that describe how a plant conducts sanitary operations before, during, and after production to prevent direct product contamination or adulteration.

Systems Audit: Unannounced on-site AMS audit of the company's effectiveness in following the QTV plan after the company has been validated.

Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the QTV plan at a facility, when properly implemented, will effectively control the hazards.

Validation Audit: Prearranged on-site AMS audit of the completeness and performance of a company's QTV plan, and the company's effectiveness in following the QTV plan.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and whether the system is operating according to the plan.

FEES

The Agricultural Marketing Act of 1946, as amended, provides AMS general authority for fee-for-service programs. The fee an applicant is charged is based on the time required by AMS personnel to review company QTV plans for AMS acceptance, travel to and from an audit site to conduct the Systems Audits, audit time, and associated administrative activities. Currently, the total time for a typical QTV systems audit and associated travel, based on recently completed QTV systems audits by two auditors, averages about 25 hours. Costs for analytical work regularly performed by a firm or an outside provider to support a firm's QTV program are the firm's responsibility. AMS will make any necessary fee rate adjustments to ensure that fees are adequate to cover the costs of providing the service and are not excessive. The overall cost of the QTV program for a participating firm is based on the frequency of the QTV audits. This frequency is based, in turn, on a firm's level of performance as determined by the periodic QTV audits. After validation, all firms begin at a "level four" rating which requires an unannounced QTV audit every two weeks. Under current QTV program requirements, a firm which demonstrates exemplary performance during all audits could advance from level four to level one in approximately seven months, or six audits, significantly reducing their costs. Level one currently requires an unannounced audit every three months. Alternatively, a firm that only did well enough to stay at level four would be audited by AMS every two weeks. This would significantly increase the cost to remain in the program compared to a firm at level one.

APPLICATION PROCESS

A. **Initial contact:** Companies that wish to participate in this program may apply in writing to AMS at Processed Products Branch, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, STOP 0247, 1400 Independence Ave, SW, Room 0726 South Building, Washington, DC 20250-0247, or telephone (202) 720-4693 to schedule a formal presentation of the program. During the presentation, AMS will provide detailed information about the service to the company's senior management.

B. **AMS Plant Survey:** Each company must satisfy and meet criteria described in an **AMS Plant Survey, Appendix A, PPB File Code 159-A-1.**

Employee training: Applicants are required to employ at least one HACCP-certified person knowledgeable in the QTV program's principles to be present **during all processing periods**. Training for HACCP certification should include a minimum of 12 hours of instruction with a certificate issued upon completion. The agenda must include the following topic areas: an overview of HACCP, hazard analysis, preventative measures, critical control point determination, sanitation SOP's, critical limits, monitoring

procedures, corrective actions, record keeping, and how to develop a HACCP team and HACCP plan. The HACCP certification must be kept on file and available to AMS at all times. More than one HACCP-certified person will be needed to cover multiple shifts, vacations and periodic travel.

D. **Required Raw Produce Supplier Verification:** The QTV Program requires that the facility's raw produce suppliers must participate in and pass an AMS Good Agricultural Practices and/or Good Handling Practices (GAP and GHP) Verification Audit. Whether one or both are required of a particular supplier depends on the role the supplier has in the supply chain. In order to fulfill this requirement, QTV applicants must supply AMS with a list of their raw produce suppliers, the suppliers' addresses and growing locations, a list of commodities, and tentative harvesting dates. Applicants must also include a listing of their supplier specifications for the raw produce used in their production processes.

E. **QTV plan:** Each applicant develops its QTV plan (which includes prerequisites and HACCP plan) and submits it for review according to the QTV Review Procedures below.

The applicant's QTV plan may be drafted by its own staff or with assistance from outside experts. The plan must include the following elements:

1. Organizational Chart and Organizational Chart Narrative;
2. Description of Product and Labels;
3. Process Flow Chart and Process Chart Narrative;
4. Hazard Analysis;
5. Raw Produce Specifications with Required AMS GAP and GHP Verification;
6. Critical Control Points Summary Table and Critical Control Point Narrative;
7. Record Keeping Methods and CCP Logs and Forms;
8. Sanitation Standard Operating Procedures and Good Manufacturing Practices (GMP's);
9. Microbiological Testing Program;
10. Pest Control Program;
11. Standard Operating Procedures (Optional);
12. Standard Testing Procedures (Optional);
13. Coding System and Recall Procedures;
14. Customer Complaint Procedures;
15. Employee Training Program for cGMPs, HACCP and Sanitation; and
16. Verification Procedures.

F. **QTV Plan Review for Suitability:** Submission and review of QTV plans will be handled using the following procedures:

1. Applicant submits QTV Plans and procedures to AMS for review.

2. AMS reviews the submitted plan and requests any necessary changes.

G. **Pre-Validation Audit Period:** before AMS will conduct a Validation Audit of a company's QTV plan, the firm must operate using its approved plan, once it has been determined that it is suitable, for a minimum of 30 days unless otherwise specified. This allows the firm time to evaluate the effectiveness of its QTV plan and generate a record of processing history. This will also provide the AMS Validation team with necessary information regarding the company's ability to follow their own written procedures. During the period prior to a validation audit by AMS, a company must perform the following:

1. Follow their QTV plan;

2. Adhere to the plan's provisions and keep all records associated with the approved QTV plan for at least 30 consecutive production days unless otherwise noted; and

3. Contact AMS as soon as they believe their plan is functioning successfully and when they have records covering at least thirty (30) consecutive production days.

AMS will contact the company to schedule a date and time for the Validation Audit.

H. **Modifications to the QTV plan:** After the QTV plan **has been reviewed** by AMS, modifications may be made under the following conditions:

1. The company **must notify AMS,** in writing (faxes and e-mails are acceptable), of any modifications in their QTV plan **before implementing** the changes. AMS acknowledgment and response to the modification will be faxed or e-mailed promptly to the applicant.

2. Any changes made to the plan due to unusual circumstances, such as to address a health or safety issue, must also be documented in a corrective action plan. AMS will assess the modifications for acceptability as appropriate and AMS will fax or e-mail a confirmation of approval or recommended changes will be to the applicant.

VALIDATION AUDIT

The validation audit will determine if all of the critical control points have been identified, whether the plan is being followed and monitored by the company, and whether it is effectively controlling the identified hazards. **Verification that the company's hazard analysis is complete and that CCP's have been properly identified, is the first step toward AMS' Validation Audit**. This audit follows the 30-day pre-validation period when the firm operated under its approved plan. Typically, it takes three QTV auditors two or three days to conduct the validation audit. This is a complete review by AMS QTV auditors of the company's QTV plan in operation. The auditors will follow the Systems Audit Checklist, which is found in this manual. Procedures for validation are as follows:

1. The number of auditors and structure of the AMS audit team will be determined by the size and complexity of the company's process.

2. The AMS audit team leader will have final authority in determining the facility's rating based on the team's findings. A consensus from all auditors is required for the classification of deficiencies.

3. Validation includes, but is not limited to, interviewing company employees, conducting paperwork reviews of prerequisite programs and the HACCP plan, recording sanitation and process observations, and determining the disposition of finished product.

4. Companies will be rated using the Systems Audit Checklist. If a company receives a Level IV or higher audit rating (see "Systems Audits" on page 9), it will qualify as a participant in the program and contractual arrangements with AMS may be finalized.

5. If a company passes its validation audit and enters into a contractual arrangement with AMS, packages of all designated products under review during the validation are eligible to bear the appropriate official mark(s) or otherwise note participation in the QTV program.

6. Companies not currently participating in the QTV program will enter the program at a facility rating of Level IV after successful validation. The results of subsequent systems audit ratings may allow changes in the facility rating and audit frequency.

SYSTEMS AUDITS

The QTV Audit Team will complete the Systems Audit Checklist in accordance with the instructions in Appendix A and Appendix B. The information recorded on the checklist is an indication of the company's performance in meeting its QTV plan, including its prerequisites.

Once a company has entered a contractual agreement, AMS will conduct unannounced Systems Audits, at the frequency identified below, to determine the company's continued adherence to its plan.

The result of each Systems Audit is based upon the findings as recorded on the appropriate Systems Audit Checklist and will be used with the following criteria to determine the facility's next rating.

Systems Audit Frequency Schedule					
Facility Rating	Audit Frequency	Maximum Number of Deficiencies Allowed			
	Schedule	Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	4-5	0
Level III	1 visit/1 month	≥8	7-10	2-3	0
Level II	1 visit/2 mos.	7	6	1	0
Level I	1 visit/3 mos.	0-6	0-5	0	0
For Facilities That Fall Below Level IV Facility Rating					
Level V	Daily or weekly as necessary	NA**	NA**	≥ 6	1

** NA = Not Applicable

A. **Level IV** - All applicants not currently participating in the QTV program will enter the program at Level IV facility rating, regardless of the audit rating. The deficiency level found by the audit will determine the facility rating level. A company will remain at a Level IV facility rating as long as they can maintain this level of performance, as defined in the table above, on each audit. After performing at a higher facility rating for two consecutive audits, at a bi-weekly frequency, the facility can achieve a Level III facility rating.

B. **Level III** - A company will remain at a Level III facility rating as long as it can maintain this level of performance, as defined in the table above, on each audit. The deficiency level found by the audit will determine the facility rating level. After performing at a higher facility rating for two consecutive audits at a monthly frequency, the facility can achieve a Level II facility rating.

C. **Level II** - A company will remain at a Level II facility rating as long as it can maintain this level of performance, as defined in the table above, on each audit. The deficiency level found by the audit will determine the facility rating level. After performing at a

higher facility rating for two consecutive audits at a bi-monthly frequency, the facility can achieve a Level I facility rating.

D. **Level I** - A company will remain at this facility rating as long as they can maintain this level of performance, as defined in the table above, on each quarterly audit. The deficiency level found by the audit will determine the facility rating level.

E. **Procedures for Facilities That Fall Below Level IV Facility Rating**

There are many potential conditions that could warrant withdrawal of service from a facility. Conditions such as the willful shipment of products that could be harmful if consumed would be cause for terminating service. In other cases, where several critical deficiencies were found and the facility undertook vigorous corrective measures, and there was no actual or imminent public harm, withdrawal of service may be warranted.

An applicant receiving a Level V facility rating has demonstrated difficulties in administering their QTV Plan.

If a Systems Audit team determines that a facility has fallen to Level V, the team leader and/or the Officer-in-Charge (OIC) of the PPB area field office will contact the National office immediately with their findings and recommendations.

A **final** decision will be made by the PPB National office and given to the Systems Audit team, which will report the decision orally and in writing to the company. The **final** decision will be made within one working day.

Facilities which fall to Level V or receive a critical deficiency at any time will be subject to an accelerated audit schedule (daily or weekly) or the withdrawal of QTV status.

If a facility does not reach Level IV rating within the next audit, which may be as soon as the next day or week, depending on the severity, AMS may withdraw its service and approval to use the QTV mark. In deciding to withdraw service, AMS will treat each occurrence, the severity of the deficiency, the surrounding circumstances, and the facility's response, on a case-by-case basis.

The following criteria will be used to determine if an **increased** frequency of audits, in lieu of withdrawal of service, will be acceptable to AMS.

1. The applicant's senior management must submit in writing a Corrective Action Plan to AMS when an accelerated audit schedule is recommended. The Plan must

detail how the facility will correct the problem and obtain a Level IV facility rating and include, at a minimum, detailed descriptions of the following:

a. A statement of the problem(s) including the root cause of the problem;
b. Identification of the person or persons responsible for correcting the situation;
c. The methods to be used to correct the problem(s); and
d. A schedule which details the time frame for correcting the problem.

2. AMS will review the corrective action plan submitted by the company.

3. The Plan will be accepted or rejected and AMS will notify the company. If accepted, AMS will tell the company how long they must remain on an increased auditing schedule.

4. At the auditor's discretion, product compliance will be verified by end-item inspection.

A company dropped from the QTV program can reapply for the service. An audit will be required which includes a determination by AMS that all deficiencies have been corrected and that changes have been implemented to prevent recurrence. A fee for the audit will be charged. All expenses for the audit will be charged to the applicant.

MICROBIOLOGICAL TESTING IN THE FACILITY

A microbiological testing program is an important tool to monitor the microbiological conditions of the facility and product throughout the entire production process. **Applicants in the QTV program are required to design and implement a microbiological testing program based on the complexity of their processes and types of commodities to be processed.** For example, the company must decide if testing will be in-house or performed by an outside laboratory, which types of testing methods to employ, which microorganisms to test for, what criteria and levels to set, etc. Testing can be accomplished by outside laboratories or in-house if there are suitable facilities and appropriate qualified staff.

The protocol for microbiological testing of the incoming product, equipment, environment, etc., is the responsibility of the plant management and should be designed for the specific facility. It is also the responsibility of the company to comply with all applicable state and federal regulations. A microbiological testing program shall, at least, address the following areas:

Incoming product;

Equipment and environment; and

Corrective actions when microbiological testing for targeted microorganisms identifies the presence of possible contamination.

Incoming product testing can be used as a tool to verify the condition of the raw product received and can contribute to a history of the supplier's ability to deliver a sound product that meets the applicant's purchase specification. One of the first steps in minimizing the microbial load is to receive and use products of the best quality and condition. Equipment and environmental testing can be used to monitor the overall performance of the company's sanitation procedures and processes. It can also be used as a gauge of the changes that can occur in a facility during processing especially when different types of products are produced.

A company must have corrective actions in place when test results are positive for the existence of a possible problem. It is the responsibility of the company to develop appropriate actions and be ready and able to initiate them when necessary. AMS auditors will review and evaluate these corrective actions as part of the systems audit.

REPORTING AND DOCUMENTATION CONTROL

A. QTV Plan, and prerequisite programs:

All company QTV plans and company-generated QTV related materials are the property of the applicant and AMS will treat them accordingly. Applicant QTV records and plans are to be protected to the extent possible with respect to the Freedom of Information Act (FOIA).

1. All company-related QTV materials in AMS possession will be marked **"CONFIDENTIAL"** and stored in a secured area by AMS.

2. Copies of the QTV Plan may be made only under the following conditions:

    a. Each page must be stamped **"CONFIDENTIAL"** in red ink.
    b. All copies must be numbered.
    c. The QTV Plan will include the statement, "This document is the property of (Place applicant name here)." for each QTV applicant.

3. Only authorized personnel may receive a copy of the QTV plan.

4. Approved QTV plans of applicants no longer in the QTV program and unapproved QTV submissions will be returned to the applicant.

B. Systems Audit Reporting and Distribution:

Auditors are encouraged to use a laptop with Lotus Notes installed for the audit in order to save time entering information and to facilitate distribution of audit information.

1. The audit team will send the completed **original** Systems Audit Checklist to the Officer-in-Charge of the area field office in which the facility is located. A copy should also be promptly mailed or faxed to the QTV Program Coordinator in the National office by the Audit Team Leader. A copy of the completed Systems Audit Checklist may be distributed to each auditor, if needed.

2. The team leader or their delegate will be responsible for promptly replicating information into the Lotus Notes database upon return to the office or remotely.

3. The audit team will give at least one signed copy of the completed Systems Audit Checklist and report of the observations from the checklist will be given to the facility during the exit briefing.

   Distribution of Systems Audit Report

   - **Original** to Area Officer-in-Charge

   - One or more copies to:
     QTV facility
     QTV Coordinator (National office)
     Each attending Auditor (optional)

AMS QTV PROGRAM SUBMISSION GUIDE

This guide is designed to provide the potential applicant with an outline for developing a QTV plan. It provides the format that must be followed as well as brief discussions on each important point in the QTV plan. Every page of the QTV plan should be stamped **"Confidential" and numbered.** QTV plans in AMS's possession remain the property of the company and are privileged and confidential.

The **plan must** be submitted in the following format. Also, potential applicants should use **Figure 1** as a table of contents for their plan.

1. Organizational Chart and Organizational Chart Narrative

2. Description of Product(s) and Labels

3. Process Flow Chart and Process Chart Narrative (See **Figure 5)**
4. Hazard Analysis
5. Raw Produce Specifications with Required AMS GAP and GHP Verification
6. Critical Control Points Summary Table and Critical Control Point Narrative
7. Record Keeping Methods and CCP Logs and Forms
8. Sanitation Standard Operating Procedures and GMPs
9. Microbiological Testing Program
10. Pest Control Program
11. Standard Operating Procedures (Optional)
12. Standard Testing Procedures (Optional)
13. Coding System and Recall Procedures
14. Customer Complaint Procedures
15. Employee Training Program for GMPs, HACCP and Sanitation
16. Verification

FIGURE 1

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1. Organizational Charts and Narrative

The facility must prepare an organizational chart demonstrating the managerial responsibility of personnel in the company. This chart must show a chain of command within the management of the facility. The organizational chart must identify the organization of facility management to illustrate how the QTV program fits into the company's organization. The relationship between the position(s) responsible for the QTV program and the production manager(s) must be indicated. The chart must also indicate all person(s) who are HACCP certified. Copies of the certificates for each HACCP certified person, should also be included in this part of the plan.

The organizational narrative should explain how each position relates to the QTV program, day-to-day QTV operations, and the relationship of the position on the chart.

2. Description of Product(s) and Labels

Description of the Product(s): A description of the finished product (e.g., product form) must be developed in order to prepare a systematic evaluation of the hazards and associated risks in a specific food and its ingredients or components. The description should include the product specification, as it could affect the hazard analysis and any repacking processes that may be required. For example:

> Product Description: Shredded lettuce packed in food grade plastic bags, 6 oz. to 1 lb. units; with an optimum shelf life of 9 days if refrigerated at 35°- 37°F; product distributed to food service and retail markets. Cases and plastic bags contain "use by" date. Product intended for consumption by general public and to be consumed directly from the container without washing or other preparation.

Originals or copies of all product labels, including front and back panels, shall be made available for auditors upon request.

Label Specifications: Use of Department of Agriculture (USDA) "approved identification" with the QTV program is only allowed after a firm enters into a contract with AMS upon successful completion of the validation audit. The QTV mark may only be used on approved products included in the QTV plan.

The QTV mark, used by an applicant operating under the QTV program, shall be a shield using at least two contrasting colors, similar in form and design to the examples below in Figures 2 and 3 or as approved by the AMS Administrator.

Figure 2

←Blue →
←White→
←Red →

QTV No. 000
Figure 3

Approved firms must submit examples of all labels, packaging and advertising materials using the QTV mark or referring to QTV to AMS for review prior to use.

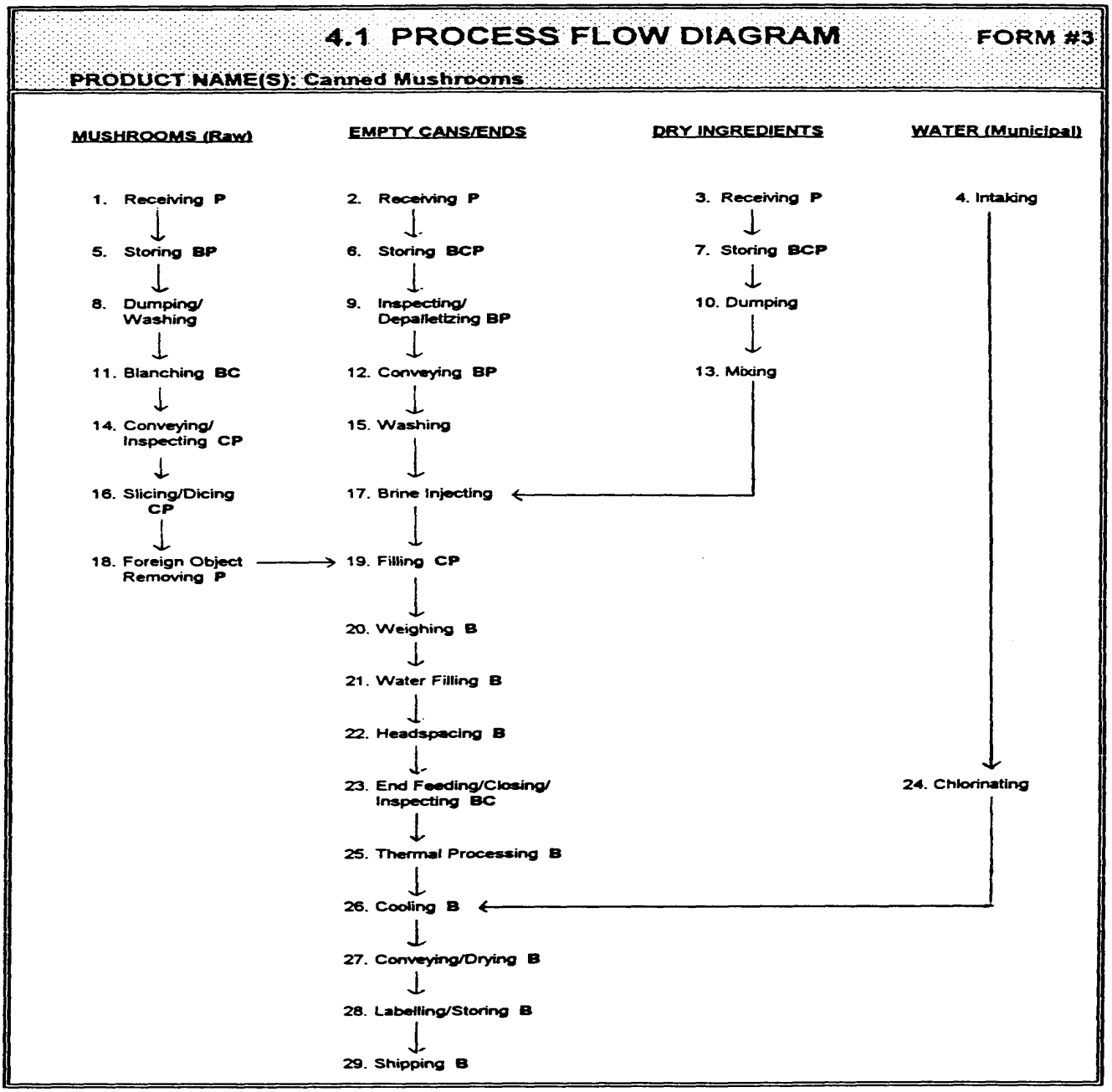
3. Process Flow Chart and Process Chart Narrative

To assist the plant in developing a QTV Plan, a process flow chart and description depicting the operational steps of how the processed product is handled throughout the plant must be made. The chart must show the steps in numerical order from when the firm takes control of the raw ingredients until the firm releases control of the finished product. For example, the process flow chart and process chart narrative will provide answers to the following types of questions:

How are raw ingredients handled from receipt into the plant (e.g., is it stored in a refrigerator or is it in frozen condition)?
How is the product handled prior to processing (e.g., is the product thawed, fresh, chilled, etc.)?
How is the product handled on the processing line(s) (e.g., is it put on a conveyor belt, washed, peeled, sorted, sized, chilled, etc.)?
How is the product stored?
How is it packaged?
How is it shipped?

The process chart narrative describes each operational step involved with a product or similar products with designations of critical control points. A process is defined as "one or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products." The process flow description should address all actions involved in the process. The company may design any type flow chart for their process. An example is shown in **Figure 4.** Other examples of flow charts for various product forms may be obtained from AMS.

Figure 4
Example of Process Flow Chart



4. Hazard Analysis

a. Identification of Hazards:

A thorough hazard analysis is one of the most important elements in developing a HACCP plan, and the QTV program requires firms to demonstrate that they have performed this step. A full discussion of the hazard analysis performed by a firm shall be included as part of the firm's QTV plan, or alternatively, a firm shall include a summary of the results of their hazard analysis in their QTV plan with a reference in the plan to the location of the full documentation of the hazard analysis performed.

There are numerous references in the literature which describe the hazard analysis process in varying levels of detail. Among these references are the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) "Hazard Analysis and Critical Control Point Principles and Application Guidelines" adopted August 14, 1997, the International Fresh-cut Produce Association's "Guidelines for Fresh-cut Produce Food Safety" and the most recent edition, currently 2005, of the Food and Drug Administration's Food Code (the food code is revised every two years). These and other references are important sources of information and guidance for performing a thorough hazard analysis. Firms should devote adequate resources and expertise to the hazard analysis process to ensure that it is comprehensive and exhaustive.

Whether temperature is a control factor at a critical control point is an issue being debated within the food safety community. Certainly, appropriate temperature control is a good manufacturing practice for refrigerated foods. AMS recognizes the merits of both sides in the debate, and QTV requirements allow a participating company to choose to control temperature of fresh-cut produce either as a CCP and part of the HACCP plan or as a regulatory control point and part of the GMPs and Standard Operating Procedures. Either way, AMS will require that temperature control be addressed by the company in their comprehensive hazard analysis and AMS will expect a QTV facility to monitor temperature as a significant factor in the safety of fresh-cut produce.

A typical hazard analysis includes:

- Identifying factors which can contribute to food safety hazards for a product. These factors include, but are not limited to, the nature of the product; the raw materials and ingredients from which it is produced; each step in the process from planting through to consumption by the consumer; equipment involved at each step; environmental conditions; and product packaging; etc.

- Identifying all potential biological, chemical or physical hazards which could affect the food safety of each product or group of similar products.

- Evaluating each potential hazard to determine if it should be addressed in the HACCP plan. The severity of a potential hazard and the likelihood of its occurrence are factors which should be considered in determining whether a particular hazard should be addressed in the HACCP plan.

A hazard analysis must consider potential hazards at all stages of the product's development, starting from planting, growing, harvesting, transporting, and storing raw ingredients, to processing, packing, storing, and shipping finished products.. The hazard analysis process identifies hazards that must be eliminated, reduced to a safe level, or prevented in order to produce a safe product. Listed below are some examples of types of hazards that could affect the product.

Biological - Harmful bacteria and viruses

Chemical - Pesticide residues, acid, cleaners, sanitizers, food grade oil, allergens, etc.

Physical - Box staples, wood, glass, rocks, insects, metal, etc.

When identifying hazards, it may be helpful to ask some basic questions. For example:

Receiving - Question: What is the product coming into the facility?
Answer: Fresh lettuce grown locally from a known supplier.

Question: What undesirable physical hazards and factors can be encountered?
Answer: Foreign material and toxic plants, etc.

Question: What undesirable chemical hazards and factors can be encountered?
Answer: Pesticide residues, toxic cleaning solutions, allergens, poisons, etc.

Steps in hazard analysis include identifying biological, chemical, and physical hazards that can be associated with products described in the product description. Additional steps are to identify the points in the process flow where the hazards can occur. These processing steps or control points are located in the facility where biological, chemical, or physical hazards may be controlled. These locations include, but are not limited to:

Raw material receiving;
Chilling room;
Inspection table;
Processing room chiller;
Metal detector;
Filler/packaging;
Storing; and
Shipping/loading dock.

NOTE: Any thermal process, used in the facility, must have been established by a qualified person(s) having expert knowledge acquired by appropriate training and experience in the processing of the product. If included in the company QTV Plan, any critical limits designed by the person(s) will be in writing and will be used in the monitoring of the processing step.

b. Critical Control Point Determination

Critical Control Points (CCPs) are determined once the potential hazards and preventative measures are identified. CCPs are those points in a facility's process where identified hazards can be prevented, eliminated, or reduced to acceptable levels. The determination of CCPs typically includes:

- Listing of hazards to be addressed in the HACCP plan;

- Identifying control measures (including preventative measures) for each hazard which can prevent, eliminate, or reduce the hazard to an acceptable level; and

- Identifying those points in the process where control measures can be applied to prevent, eliminate, or reduce the hazard to an acceptable level.

5. Raw Produce Specifications with Required AMS GAP and GHP Verification

This section includes a listing of the facility's supplier specifications for the raw produce used in its production process. The first step in determining supplier performance is to have established, objective specifications that are communicated to the supplier.

The QTV Program requires that the facility's raw produce suppliers must participate in and pass an AMS Good Agricultural Practices and Good Handling Practices (GAP and GHP) Verification Audit. In order to fulfill this requirement, QTV applicants must

supply AMS with a list of their raw produce suppliers, the suppliers' addresses and growing locations, list of commodities, and tentative harvesting dates.
GAP and GHP is an audit verification program that helps the produce industry verify voluntary adherence to the Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This program is an audit based service. It assesses a supplier's efforts to minimize the possibility of contamination of fresh fruits, vegetables and nuts by microbial pathogens. It does not assure that the product is free from microbial contamination. Audits are intended to occur at the supplier on a quarterly basis depending on harvesting dates and locations. The responsibility for continuing product safety and the continued observance of practices leading to a minimized possibility of microbial contamination rests with the supplier.

To inquire about GAP and GHP audits please contact USDA, AMS, Fruit and Vegetable Programs, Fresh Products Branch; 1400 Independence Avenue, SW; Room 1661, Stop 0240; Washington, D.C. 20250-0240; Phone: (202) 720-5870 or (202) 720-2482.

6. Critical Control Points (CCP) Summary Table and Critical Control Point Narrative

Figures 5 and 6 show examples of a CCP summary table and narrative for listing the elements of a CCP in the HACCP plan and should be used for QTV plan submission. **Figure 5** is an example of a summary table used as a quick reference listing all numbered CCP's and the information pertaining to each. The table provides information in summary form for the following required steps: CCP (location), Hazard, Preventive Measure(s), Critical Limit, Monitoring Procedures, Corrective Action, Records, and Verification. The CCP narrative is an extension of the summary table with each CCP having its own page. Each narrative is titled by its CCP number and area of concern. The narrative should cover everything found in the summary table and allow for a more in-depth explanation of the processes in each of the steps. **Figure 6** is an example of the narrative description for each CCP. The narrative should completely explain the following:

a. Preventive (Control) Measures

Identification and description of the preventive measures determined for each of the identified significant hazards. Preventive measures prevent, reduce, or eliminate a significant hazard. These measures can include, but are not limited to:

Vendor certification of pesticide residue-free raw product;
Periodic visits to suppliers' growing fields and harvesting operations;
Pesticide residue testing;
Purchasing specifications;

Maintenance of proper temperature;
Refrigeration maintenance;
Training programs for employees;
Calibration of equipment (scales, thermometers, metal detector);
Proper time and temperature control;
Production scheduling;
Adherence to current Good Manufacturing Practices;
Physical inspection;
Certificate of water potability;
Proper packaging;
Supervisory checks; and
Inventory control.

Employee training is a preventative measure that is paramount in launching and maintaining a HACCP plan. HACCP is built on the premise of having a pro-active or preventative system which identifies and corrects problems before the product is released from the facility. In order to accomplish this, a facility must have trained employees able to recognize and prevent problems as they arise, are required.

b. Critical Limits

A critical limit as defined in the Food Code means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to minimize the risk that the identified food safety hazard may occur.

Under critical limits, show the "operating range" that is to be met (see **Figure 6).** There may be more than one critical limit for a CCP. If during production, value(s) are outside of the critical limit(s), the process will be out of control and a potential hazard can exist.

The critical limit is used as a marker, which if exceeded, alerts the firm that a potential hazard/problem exists at a particular CCP. If a critical limit is exceeded, the firm will weigh the possible solutions and decide what to do to correct the problem.

Criteria most frequently utilized for limits include temperature, time, available chlorine, pH, titratable acidity, preservatives, salt concentration, water activity (A_w), and other criteria. Critical limits can be quantitative (i.e., a numerical value) or qualitative (e.g., evidence of decomposition as determined by an organoleptic evaluation). They can be a maximum, minimum, or range value.

Many different types of critical limit information may be needed for control of a CCP.

It is important to establish reasonable critical limits that will ensure control of the potential hazard. The firm may want to set limits that are more stringent than regulatory limits or product purchasing specifications to ensure that the product will be acceptable.

c. Monitoring Procedures

Monitoring procedures are the scheduled evaluation and/or observations recorded by the firm to report the results at each CCP. Monitoring results must be documented. Failure to exercise control of a CCP which includes proper monitoring and documentation of the CCP is a critical deficiency in the Program.

A critical deficiency is a serious deviation from Plan requirements that compromises the safety of the product. Because of the potentially serious consequences of a critical deficiency, monitoring procedures at each CCP must be effective.

Continuous monitoring is possible with some types of physical and chemical methods and should be applied. However, when this is not possible, it is necessary to establish monitoring intervals that will reliably indicate that the critical limit(s) are being met and the hazard is under control.

For each CCP, list the procedures to be used to monitor the control of that specific CCP. When listing these procedures, be specific. List:

i. What is the monitoring procedure;
ii. Who will perform the procedure;
iii. What is the frequency at which the procedure will be followed; and
iv. Any associated criteria for the procedure. For example; sampling plans used, definitions of samples and/or lots, etc.

d. Corrective Actions

Corrective Actions are defined as procedures to be followed when a deviation occurs. When critical limits are exceeded at a CCP, corrective actions must be taken to eliminate the hazard created by the deviation. These actions must also ensure proper disposition of the product involved. Corrective action for each critical limit of a critical control point must be developed. This is due to variations in product and the diversity of associated deviations.

NOTE: After a facility executes a Notice of Unusual Occurrence and Corrective Action (NUOCA), it must follow up by calling the PPB National office, within a reasonable amount of time, (next business day) to report the corrective action taken. (See definitions)

Corrective Actions will involve:

i. A statement of the anticipated problem (usually in an "If...then" format);
ii. Procedures for handling of the product;
iii. Identifying the person responsible for the corrective action;
iv. Testing to establish the acceptability of affected product (if applicable);
v. Final disposition of the product; and
vi. Documentation and signatures.

e. Records

For each CCP, records are created demonstrating that monitoring procedures and corrective actions are being followed. The types of records that would demonstrate adequate documentation that CCP's are being controlled are:

- Records showing that CCP's are being monitored. **The critical** limit should be incorporated on the monitoring record as a constant reminder to the examiner or observer.

- Records documenting deviations from the HACCP plan and the corrective actions taken when critical limits are exceeded. These records should include disposition of the products(s) involved. If the decision is made to use the product, indicate under what conditions it was maintained pending evaluation. **All reports of corrective actions must be kept in a separate file or log with copies attached to the monitoring record where the problem occurred.** Note: Records showing that instrumentation or other equipment necessary to the monitoring process has been properly checked for accuracy and reliability, and is being properly maintained should also be included with each corrective action report.

f. Verification Procedures

Verification consists of periodic review by the company to determine the overall effectiveness of its QTV plan.

Verification helps confirm that all hazards were identified, that the appropriate CCP's were selected, and that the QTV plan is functioning properly. Verification measures may include:

i. Inspection of the facility as to conformance with the facility's QTV plan and established federal regulations;

ii. Records review, including daily review of all CCP's;

iii. Physical, chemical, and sensory examinations of product to ensure conformance with QTV plan criteria;

iv. Testing for conformance with microbiological criteria where established; and

v. Inspection of a contract laboratory to ensure that the samples received for analysis are being examined correctly.

A facility's verification of its QTV plan should involve substantial self-monitoring of critical control points and other areas. It may include analysis of the raw material or in-line environmental testing depending on the possibility of emerging problem areas. Analysis of samples can be performed in-house at the facility or the samples can be analyzed by a contract laboratory.

Figure 5
Example of Listing of Critical Control Points

Critical Control Point	Hazard	Preventative Measure(s)	Critical Limit	Monitoring Procedures	Corrective Action	Records	Verification

Figure 6
Example of Critical Control Point Narrative

Critical Control Point 4 - Metal Detector

Hazard(s):

Preventative Measures:

Critical Limit:

Monitoring Procedures:

Corrective Actions:

Records:

Verification:

7. Record Keeping Methods and CCP Log and Forms

Maintenance of all logs and forms is an essential part of the QTV program. Documentation provides a history and establishes that processes are in control. For auditing purposes it is crucial that documents be readily available for review. A detailed description of where documents are located and filed is required.

> Example: Documents for CCP5 are located in the QC manager's office, brown metal filing cabinet #3, drawer 3b.

All documents related to CCPs should be identified by their corresponding CCP number and document creation date. The CCP number identifies that the document is utilized for that particular area. The date acts as an identifier for revisions of the documents. Copies of all forms and documents that are used in the QTV program will be maintained in the QTV plan. A listing of all CCP logs and forms used in the program will aid the auditor when reviewing documentation. Developing an accurate record keeping system that demonstrates control over critical control points will:

a. Advise facility management and AMS of the performance of an applicant's QTV plan on a day-to-day basis;

b. Provide evidence of proper and safe operation; and

c. Serve as a mechanism for indicating potentially serious problems and assisting the responsible individuals in the determination of proper corrective action.

An efficient filing system must be set up for all QTV-related records and forms. **CCP monitoring records and CCP deviation and corrective action records shall be maintained for a period of six months to one year after the shelf-life of the product; and records for prerequisite programs maintained for a period of one year**. Annual verification audits, which are in-depth evaluations of the HACCP system to ensure that the prerequisite programs and HACCP plan are being implemented as designed, should be taken into account when considering record retention time periods. All of the records and forms in this filing system must be accessible to AMS at all times.

8. Sanitation Standard Operating Procedures

Equally important but distinct from the CCPs are the Sanitation Standard Operating Procedures (SSOPs). Applicants must develop standard operating procedures for daily,

weekly, and otherwise periodic sanitation practices and procedures at their facility. Standard operating procedures should be specific as to how sanitation practices are performed. The QTV plan should list who will perform these procedures, the frequency of the procedures, and any associated information. Standard operating procedures should be written with the following assessment areas and others, as appropriate, in mind:

Structure and Layout;
Maintenance;
Cleaning and Sanitizing;
Personnel;
Restrooms;
Water Supply;
Ice;
Chemicals;
Ventilation; and
Waste Disposal.

Monitoring procedures for the SSOP's should be established. These monitoring procedures should include who will perform the monitoring, the frequency of monitoring, and any forms or records used to document this monitoring.

All the above areas will be evaluated by AMS using the appropriate form(s) for the applicant's type of operation.

These sanitation assessment areas are cross-cutting throughout the facility. This is why the QTV-based Submission Guide discusses items relating to "process" factors separately from "sanitation."

9. Microbiological Testing Program

This is a description of the applicant's microbiological testing procedures, used to monitor their process, product, and sanitation techniques to determine if they are effective in controlling food safety hazards and in compliance with the applicable regulatory guidelines. **Applicants in the QTV program are required to design and implement a microbiological testing program based on the complexity of their processes and types of commodities to be processed.** The microbiological testing procedures may include:

The types of organisms to test for;
The types of tests used and how to count the organisms;
In-house testing and outside laboratory testing;
Incoming product testing;

Environmental and equipment testing;
Finished product testing;
Sampling conventions that will be used; and
The baseline standards employed.

The facility should identify corrective actions it will take if or when microbiological testing finds contamination of product, equipment, and/or facility, or that an established microbial threshold was exceeded. Such corrective steps should include, but are not limited to:

Sanitizing affected areas and equipment;
Reviewing processing and/or sanitation procedures;
Reviewing supplier records and area; and
Holding or destroying contaminated product.

AMS recognizes the use of outside analytical laboratories for microbial testing and food safety training.

Note: Microbiological testing alone may be an inadequate means to monitor a CCP. Test results are usually available after the product is out of the facility's control. Testing can be used effectively, however, to verify that processes and sanitation techniques are effective.

10. Pest Control Program

The Pest Control program should identify how a company is effectively managing pest control in their plant. It is important to identify who has the responsibility and the authority to implement, evaluate and make decisions regarding the pest control program. If an outside contractor for pest control is being used, the name of the company, their procedures and methods, how often do they return to check traps and a map of where all the traps have been placed, should be documented.

A pest control program shall include, but is not limited to, the following:

- Sanitation, housekeeping and good manufacturing practices;
- Facility and grounds inspection and surveillance;
- Proper facility design, maintenance, and physical pest exclusion;
- Proper stock handling and warehousing techniques;
- Appropriate use of mechanical pest control techniques and trapping strategies; and
- Proper selection and application of pesticides.

Documentation shall be maintained to provide evidence that a pest control program is in operation, surveillance is on going, and verification is taking place.

11. Standard Operating Procedures

This section includes the procedures for monitoring critical control points and other processes in the QTV program if more detail is needed and it is referenced in the QTV plan. The purpose of this section is to give applicants the option of cataloging their procedures. The Standard Operating Procedures (SOP's) should include, but are not limited to: details on the procedures for monitoring temperature, pH, chlorine, etc. Each SOP must identify the procedure, its location, equipment, method, documentation, and accountable personnel, including who will verify the SOP.

12. Standard Testing Procedures

This section includes the methodology of the tests used to implement the SOP's. The purpose of this section is to describe test procedures and equipment. Standard Testing Procedures (STP's) include, but are not limited to: details of the type of chlorine test(s) used, type(s) of thermometer(s) used, etc. Each STP must identify the procedure or equipment and corresponding SOP it is associated with.

13. Coding System and Recall Procedures

A detailed explanation of the plant's product coding system and an example of each type of code used should be included. Recall procedures for identifying, locating, and retrieving products are an important tool used by industry to protect their customers. The Food and Drug Administration (FDA) has provided guidelines which direct how recalls are initiated and carried out. A copy of the facility's recall program must be submitted along with the QTV plan.

Each recall program should contain a current written contingency plan for use in initiating and affecting a recall, coding strategy that makes positive lot identification possible, and a listing of product distribution records that are necessary to facilitate the location of a recalled product. See 21 Code of Federal Regulations (CFR) Part 7 for more information and requirements.

14. Consumer Complaint Procedure

This section includes a consumer complaint file and a standard operating procedure for handling consumer complaints. A company must have a procedure to deal with customer complaints. AMS will not routinely review specific complaints, however, it may do so as a result of a food safety complaint or incident.

15. Employee Training Program

An overview of the organization's training program should be provided in the QTV plan. This should include the type of training provided, frequency, and how the training is documented. A comprehensive training program includes, but is not necessarily limited to, training in the areas of:

Current Good Manufacturing Practices (GMP's);
Sanitation;
Hazard Analysis Critical Control Point (HACCP); and
Qualified Through Verification (QTV).

The program should also emphasize each employee's role and responsibilities in these areas. In addition, retraining of employees should be addressed. The training program description should answer questions such as:

What determines the need for an employee's retraining?
How is retraining accomplished?
Is there documentation supporting the need for retraining?
When did retraining occur and is it documented?

16. Verification

There are three levels of verification with corresponding frequencies that will strengthen a firm's reliability in the QTV program. These three types of verifications are categorized by their frequencies: daily, monthly or quarterly, and annual.

Daily: A supervisor not involved in documenting plant performance under the QTV plan, should verify all QTV-related records each day to ensure that the operating decisions made by plant personnel are consistent with QTV plan requirements. The supervisor should follow-up when inconsistencies occur. That supervisor should also review any reports of critical limit deviations and follow-up corrective action reports, and ensure that the QTV plan is followed. The review should be documented by the supervisor's signature on reports and forms completed by plant personnel.

Monthly /Quarterly: This periodic review verifies the HACCP plan and other intermittent records. This particular type of verification is designed to verify the proper implementation of QTV controls and identify trends that might indicate problems.

Annual: The annual verification should review the QTV plan and verify that any changes to the plan have been identified and evaluated for effectiveness. The review should include, but is not limited to, the following records: prerequisite programs, SOP's, lists of product ingredients and suppliers, process flow charts, QTV record forms, and filing procedures and the QTV plan.

The annual verification is also an evaluation of the overall HACCP program. The hazard analysis should be reevaluated thoroughly to determine:

- Whether there are any new scientific data that impact upon the operation;

- Whether all processes, product, or other changes are adequately considered and addressed in the current hazard analysis;

- What progress has been made to provide data where questions are raised about potential hazards and the likelihood of their occurrence; and

- Whether the best control methods are being applied in the proper context (prerequisite programs versus **CCP).**

The HACCP plan should be evaluated to verify that the appropriate critical limits are being applied. A report should be generated documenting that:

QTV controls including HACCP CCP's have been verified;
Changes have been made to improve implementation as applicable; and
The QTV plan and related documents are up-to-date.

It is also recommended that re-signing and re-dating of the SOP's, hazard analysis, and the QTV plan be done to document that this annual verification activity has been performed.

NOTE: A firm must have an adequate quality assurance program which can provide the infrastructure to support all the elements in the QTV program. Appropriate quality assurance operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Appendix A
Systems Audit Checklist

This appendix provides instructions for completing the Systems Audit Checklist. The Systems Audit Checklist will be used by AMS auditors during Validations and Systems Audits. When using the Lotus Notes database AMS auditors should see "Help" and "Using this Database" for instructions.

AMS auditors will perform a Validation or Systems Audit and note any deficiencies. Deficiency areas include a company's adherence to their QTV plan, completeness of records, and sanitation.

The Systems Audit Checklist should be completed as follows:

1. Enter the complete name and address of the firm in the **Name and Address of Facility Inspected** area.

2. Enter all of the owners (company or individuals) in the **Facility Owner** area.

3. Enter the associated products which are being Validated or Audited in the **Products Concerned** area. The associated products can be taken from the products list in the submitted plan.

4. Enter the names of all auditors that are taking part in the Validation or Systems Audit in the **Name(s) of Auditors** area.

5. If a representative from the firm or other individual is accompanying the AMS audit team during the validation or audit, enter the individual's name and title in the **Name and Title of Accompanying Individual** area.

6. Enter the Processed Products Branch (PPB) office where the facility is located in the **PPB Office** area.

7. Enter the State where the facility is located in the **State** area.

8. Enter the QTV facility number, if applicable, that has been assigned to the facility in the **Facility Number** area.

9. Enter the month, day(s), and year the Validation or Systems Audit has taken place in the **Date (mm/dd/yyyy)** area. If the validation or audit takes more than one day, include **all** of the dates in the appropriate area.

10. Enter the phone number of the facility in the **Phone Number** area.

11. Each deficiency found during the validation or audit will be checked in the appropriate box on the Systems Audit Checklist. The weight of the deficiency (Minor, Major, Serious, Critical) **cannot** be changed. There are 31 areas on the Checklist that have two or more boxes. If a deficiency is found in that area, the auditors must agree on the severity of the deficiency and select the appropriate box. For all items of Section A, Records, except section A.4., "Falsification of records," use the following guidance for determining the weight of the deficiency, based on the percentage of records that were found to be inaccurate:

    SERIOUS: Equal to or greater than eight (8), but less than 10 percent of records; and

    CRITICAL: Equal to or greater than 10 percent of records.

NOTE: A record is a document which records the results of monitoring procedures or corrective actions. To determine the percentage of records, divide the total number of daily records or forms for that procedure, by the number of inaccurate records. Example: You are reviewing records for the month of May. CCP 1- Receiving Form, is missing information for two checks on Monday, May 22. Tuesday through Friday make up the rest of the work week, two shifts each day. There are a total of 22 records for the month of May for CCP-1, where one record covers two shifts. Therefore, one divided by 22 equals 4.5 percent.

12. An explanation for each box checked on the Systems Audit Checklist will be recorded under the **Systems Audit Listing of Observations** section, **except** when entering the information into Lotus Notes. In Lotus Notes, record the explanation in the area where the deficiency is scored. This explanation will list out each deficiency and include the specifics of each deficiency and how it relates to the QTV plan. In this case, observations and follow-up comments **not** associated with a deficiency are listed under the "Listing of Observations" section. For example, if monitoring procedures are not being followed at several critical control points, the box under B., PROCEDURES, "Monitoring Procedures not followed" would be checked. "The Systems Audit Listing of Observations" would then have each instance of this deficiency noted in detail unless you are using Lotus Notes, then the deficiency would be noted in the area within B.1. This detail would include specifics such as the critical control point, person(s) not following the monitoring procedures, and references to the monitoring procedures in the plan.

Note: Be sure to follow up on previous audit deficiencies. Include a summary of discussions with management and suggested timetables. Also note any changes and improvements of the facilities.

13. Total the Minor, Major, Serious, and Critical boxes that have been checked in the **SUMMARY: Total Deficiencies** area.

14. Check the applicable symbol {□ **and** ( )} in the **"Beginning Facility Rating Level"** area. Use the totals of the present audit to arrive at the **"Audit Rating Level"** and check the applicable symbol {□ **and** ( )} for the facility. Enter the new facility rating in the **"Final Facility Rating"** area and check the applicable symbol {□ **and** ( )}. The facility will be placed on a Systems Audit frequency as they correspond to the table on the checklist. Lotus Notes will automatically compute the final level.

15. All AMS auditors will sign their names and enter the date in the **Auditor(s) Signature and Date(s)** area. In Lotus Notes, type the name of each auditor in the signature area and sign above the typed name.

SYSTEMS AUDIT CHECKLIST		
Name and Address of Facility Audited	PPB Office:	
	State:	
	Facility Number:	
Facility Owner (Company or Individual):	Date (mm/dd/yyyy):	
Products Concerned:	Phone Number:	
Names of Auditors:	Check one:	
Name and Title of Accompanying Individual:	Validation Audit: ☐ System Audit: ☐	

Minor Deficiency (MIN): A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.

Major Deficiency (MAJ): A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in an unsafe product.

Serious Deficiency (SER): A deviation from the QTV plan that has the potential to lead to an unsafe product and is highly objectionable (e.g., modification to critical limits without approval, or certified trained personnel not available).

Critical Deficiency (CR): A deviation from the QTV plan requirements or other conditions that have lead to an unsafe product or that brings into question the underlying commitment of the firm to the QTV program (e.g., falsified documents, or interference with the audit).

Adherence to QTV Plan				
A. RECORDS	MIN	MAJ	SER	CR
1. Records are not up-to-date.		☐	☐	
2. Records are inaccurate.			☐	☐
3. Records are not available for inspection.			☐	☐
4. Any documents or records are falsified.			☐	☐
B. PROCEDURES	MIN	MAJ	SER	CR
1. Preventive Measures not followed.			☐	☐
2. Monitoring Procedures not followed.			☐	☐
3. Corrective Action not taken.			☐	☐
C. OTHER	MIN	MAJ	SER	CR
1. Modification to QTV plan used without approval.		☐		
2. Modification to critical limits without approval.			☐	☐
3. Certified trained personnel not available.			☐	
4. QTV Plan Prerequisite Programs and/or Procedures not followed.		☐	☐	☐

Facility Sanitation				
1. PEST CONTROL	MIN	MAJ	SER	CR
1.1 Harborage and attractant areas present.		□		
1.2 Pest control measures not effective. 1.2.1 Exclusion		□		
1.2.2 Extermination.			□	□
2. STRUCTURE AND LAYOUT	MIN	MAJ	SER	CR
2. 1 Grounds condition can permit contamination to enter the facility.	□			
2.2 Facility. 2.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized; doesn't preclude contamination.		□	□	
2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated			□	□
2.3 Equipment and utensil design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product or primary packaging material.		□	□	
3. MAINTENANCE	MIN	MAJ	SER	CR
3.1 Condition of roof, ceiling, walls, floors or lighting not maintained; lights not protected.				
3.1.1 Area directly affecting product or primary packaging material.			□	□
3.1.2 Other.	□	□		
3.2 Insufficient Lighting	□			
3.3 Equipment, primary packaging material, and utensils not maintained in proper repair or removed when necessary. 3.3.1 Product contact surfaces.		□	□	
3.3.2 Other.	□	□		
4. CLEANING AND SANITIZING	MIN	MAJ	SER	CR
4.1 Product contact surfaces not cleaned and sanitized before use.			□	□
4.2 Non-product contact surfaces not cleaned before use.		□	□	
4.3 Inadequate housekeeping.	□	□		
4.4 Cleaning methods permit adulteration or contamination.			□	□
5. PERSONNEL	MIN	MAJ	SER	CR
5.1 Processing or food handling personnel do not maintain a high degree of personal cleanliness.		□	□	
5.2 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.			□	□
5.3 Controls. 5.3.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.			□	
5.3.2 Hand/foot washing and hand/foot sanitizing stations not present or conveniently located.			□	□
6. RESTROOMS	MIN	MAJ	SER	CR
6.1 Insufficient number of functional toilets.	□			
6.2 Inadequate supplies.			□	
6.3 Inadequate housekeeping.			□	□

7. WATER SUPPLY	MIN	MAJ	SER	CR
7.1 Unsafe water supply.				☐
7.2 Inadequate protection against backflow, back-siphonage, or other sources of contamination.			☐	
7.3 Inadequate supply of hot water.	☐	☐		
8. ICE	**MIN**	**MAJ**	**SER**	**CR**
8.1 Not manufactured, handled, or used in a sanitary manner.			☐	☐
9. CHEMICAL	**MIN**	**MAJ**	**SER**	**CR**
9.1 Chemical (s) improperly used or handled.			☐	☐
9.2 Chemical (s) improperly labeled.			☐	☐
9.3 Chemical (s) improperly stored.			☐	
10. VENTILATION	**MIN**	**MAJ**	**SER**	**CR**
10.1 Condensation 10.1.1 Areas directly affecting product and/or food contact surfaces and/or packaging material.			☐	☐
10.1.2 Nonfood contact areas		☐		
10.2 Adequate air exchange does not exit.	☐			
11. WASTE DISPOSAL	**MIN**	**MAJ**	**SER**	**CR**
11.1 Improper disposal of: 11.1.1 Sewage.			☐	☐
11.1.2 Processing waste.			☐	
Summary	**MIN**	**MAJ**	**SER**	**CR**
Total Deficiencies				

Beginning Facility Rating Level	Audit Rating Level	Final Facility Rating Level
☐ Level IV ( ) 0 audit above level ☐ Level III ( ) 1st above level ☐ Level II ☐ Level I	☐ Level IV ☐ Level III ☐ Level II ☐ Level I	☐ Level IV ( ) 0 audit above level ☐ Level III ( ) 1st above level ☐ Level II ☐ Level I
Facilities That Fall Below Level IV Facility Rating		☐ Level V
Auditor(s') Signature(s) and Date(s)		
Reviewer's Signature and Date		

Systems Audit Frequency Schedule

Facility Rating	Audit Frequency	Maximum Number of Deficiencies Allowed			
	Schedule	Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	4 -5	0
Level III	1 visit/1 month	≥8	7-10	2 -3	0
Level II	1 visit/2 mos.	7	6	1	0
Level I	1 visit/3 mos.	0-6	0-5	0	0
For Facilities Below Level IV Facility Rating					
Level V	Daily or as necessary	NA**	NA**	≥ 6	≥ 1

**NA = Not Applicable

File Code 151-B-4
February 2008 (Revised)

Systems Audit

Listing of Observations

Date of Audit:_____

List Deficiency Step and Classification	Reasons for Deficiency Classification(s)

Appendix B

Systems Audit Checklist Reference

Adherence to QTV-based Plan

A. RECORDS

REASON:
Records are used to record the success of the facility's QTV system. Non-compliance in record keeping can make it difficult to prove control of the process.

1. Records are not up to date.

COMPLIANCE:

MAJOR: Entries must be made as they are measured. All time schedules outlined in the QTV plan must be maintained.

SERIOUS: All labels must be up-to-date. All labels must be kept on file by the firm.

2. Records are inaccurate.

COMPLIANCE:
All entries must be accurate or they are meaningless. If calculations or the times measurements are taken, etc., are not correct, or illegible, the box for this deficiency should be checked. If incorrect entries are made on a record, a line must be drawn through it, the correct entry should be made, and the new entry should be initialed by the person making the entry. White-out (correction fluid) and pencils must not be used. If an auditor finds records, deemed to be acceptable by the company, that are unacceptable, the deficiency will be checked at the following level (for more information on the percentage of records verified, see note on page 35.):

SERIOUS: Equal to or greater than 8 percent, but less than 10 percent of entries;

CRITICAL: Equal to or greater than 10 percent of entries.

3. Records are not available for inspection.

COMPLIANCE: Records are readily available to AMS auditors.

SERIOUS: If the firm does not promptly provide the applicable records for review or records are misplaced, they are not in compliance with this item.

CRITICAL: If portions of records are not available, the company **is not** in compliance with this item.

4. **Any documents or records are falsified.**
COMPLIANCE: Documents or records are executed truthfully and correctly.

SERIOUS: If an entry on a record was shown to be corrected with correction fluid or other means of obliteration, this will be considered an inaccurate entry

CRITICAL: If records have been falsified.

B. PROCEDURES

REASON:
The procedures outlined in a company's QTV plan must be followed as written. The plan was approved by AMS as a whole, not procedure-by-procedure. Not following a procedure could affect an entire critical control point.

1. **Preventive measures not followed.**
COMPLIANCE:
Although no documentation is required, preventive measures provide a buffer for the company in keeping control of a particular critical control point. Not following these measures affects other subsequent procedures at that critical control point. If any preventive measure outlined is not followed and if a corrective action report is not filed, the company is not in compliance for this item. Use for CCP's only.

SERIOUS: A measure that is not adhered to, that could potentially lead to an unsafe product.

CRITICAL: A measure that is not adhered to, that has led to an unsafe product.

2. **Monitoring procedures not followed.**
COMPLIANCE:
Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the company is not in compliance with this item.

SERIOUS: a procedure that is not adhered to, that could potentially lead to an unsafe product.

CRITICAL: a procedure that is not adhered to, that has led to an unsafe product.

3. Corrective action not taken.

COMPLIANCE:
If deviations occur or when QTV plan procedures are not followed, the company must take corrective action and document it in a corrective action report or a Notice of Unusual Occurrence and Corrective Action (NUOCA).

SERIOUS: Corrective action procedures not followed or documented but product still in control of the facility.

CRITICAL: No corrective action taken and product not in the facility's control.

C. OTHER

1. Modification to QTV plan used without approval.

COMPLIANCE: Facilities are required to immediately advise AMS when implementing tests or new procedures. This includes all procedures at critical control points, sanitation procedures, verification procedures, plan modifications, adding new products or styles and consumer complaint procedures. Exceptions will be allowed for those procedures the company can justify that were necessary to avert or control a public safety or health situation provided a corrective action report is on file for the incident and a request for plan modification is filed with AMS within a 24-hour period.

MAJOR: Any change in procedures without AMS approval, whether they are written or not, will be considered non-compliance by the company for this item. (MAJOR)

2. Modification to critical limits without approval.

COMPLIANCE:
No modifications to critical limits will be accepted without prior approval from AMS. Any deviation noted for this item will be considered non-compliance.

SERIOUS: No record of prior approval and has the potential to lead to an unsafe product.

CRITICAL: No record of prior approval and unsafe product has been shipped to consumers.

3. Certified trained personnel not available.

COMPLIANCE: Each company must employ a person whose HACCP certification AMS recognizes for this program. At least one HACCP-certified person is **required to be present** during production.

SERIOUS: HACCP-certified person not present during production and/or copies of all HACCP certificates not on file with the company and QTV plan.

4. QTV Plan Prerequisite Programs and/or Procedures not followed.
COMPLIANCE: Prerequisite programs and/or procedures, including Good Manufacturing Practices, Good Agricultural Practices and Handling Practices that address operational conditions specific to the QTV plan, provide the foundation for the HACCP system and the QTV plan. Not following the prerequisites stated in the plan means that the system may be compromised and the company is not in compliance for this item.

MAJOR: Elements of prerequisite programs are not adhered to, that may indirectly affect the safety of the product.

SERIOUS: Criteria for compliance not adhered to with potential to impact QTV program.

CRITICAL: Criteria for compliance not adhered to which will significantly impact QTV program.

Facility Sanitation

1. PEST CONTROL
REASON:
The presence of rodents, insects, and other animals in the facility should not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

1.1 Harborage and attractant areas present.
COMPLIANCE:
The facility and grounds are to be free of harborage areas. Harborage areas include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are properly constructed. (MAJOR)

1.2 Pest control measures not effective.

1.2.1 Exclusion
COMPLIANCE:
Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise

sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for air curtains for entrances in food establishments.

MAJOR: Strip curtains must run the entire width of the opening with sufficient overlap between flaps (½ inch). In addition, effective efforts should be made to keep birds from areas of the plant where food is transferred or processed, or packaging material is stored.

1.2.2 Extermination

COMPLIANCE:

Birds--Nesting areas which pose a hazard to food or packaging material must be eliminated.

Insects--There should be not more than an insignificant number of insects present in the facility. Approved insecticides and/or devices should be used whenever insect populations become noticeable.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal dropping present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance. (SERIOUS)

CRITICAL: Any evidence of pest contamination or presence on food contact surfaces including packaging, ingredients, raw materials, or product.

2. STRUCTURE AND LAYOUT

REASON:

Care must be taken to not allow contamination of a food product through indirect means. Improperly maintained outside conditions can cause plant contamination through a variety of means, such as airborne, foot traffic, etc. In addition, an improper layout of operations within a facility can inadvertently result in adulteration or contamination of the food product through employee traffic, wind drafts, or other means.

2.1 Grounds condition can permit contamination to enter the facility.

COMPLIANCE:

MINOR: There shall be no condition on the grounds such as dusty roads or parking lots, mud puddles, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc. Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls, and ceilings, as well as for visual inspections.

2.2 Facility.

2.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized.
COMPLIANCE:

MAJOR: If the rooms (including restrooms and employee break rooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

SERIOUS: If facility's design, construction, location, or materials could contribute to contamination of the product.

2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.
COMPLIANCE: There must be sufficient separation between different activities in the storage, processing, packaging and handling of food products. This includes the complete separation of eating areas or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food surfaces
if exposed. In addition, the layout of the facility should not be such that product contamination is likely due to heavy employee traffic through work areas.

SERIOUS: If insufficient separation between different activities in the storage, processing, packaging and handling of food products are found.

CRITICAL: If product contamination exists due to insufficient separation between different activities in the storage, processing, packaging and handling of food products.

2.3 Equipment and utensil design, construction, location, or materials cannot be readily cleaned sanitized; does not preclude product contamination or adulteration.

COMPLIANCE: Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it does not contribute to the contamination of product and so that it can be easily taken apart for regular cleaning and inspection. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for the intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

MAJOR: If equipment and utensil design, construction, location, or materials cannot be readily cleaned, and/or sanitized.

SERIOUS: If equipment and utensil design, construction, location, or materials could contribute to contamination of the product.

3. MAINTENANCE

REASON:

Food handling establishments must be maintained at a high level. Deterioration of the building such as a leaky roof, cracks or depressions in the floor, or unprotected glass lighting fixtures can be reservoirs for bacteria or can cause direct contamination of food products being manufactured in the facility. Equipment and utensils that are not well maintained also pose a risk of bacterial harborage or direct product contamination. Conditions such as rusted or pitted product-contact surfaces and frayed conveyor belts are examples of non-compliance.

3.1 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.

3.1.1 Areas directly affecting products or packaging material.

COMPLIANCE: For those areas that will directly affect product or primary packaging materials, (i.e., packaging immediately surrounding product), the roof, ceilings, walls, floors, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

SERIOUS: Area is highly objectionable and could potentially lead to an unsafe product.

CRITICAL: Area that leads to an unsafe product or results in product contamination.

3.1.2 Other.

COMPLIANCE: For areas in the facility other than in 3.1.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.

MINOR: A deficiency that is not likely to reduce a facility's ability to meet acceptable sanitation requirements.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

3.2 Insufficient lighting.

COMPLIANCE: Lighting in areas where food is handled, processed, stored, packaged, or displayed and where sanitation is performed, must be adequate to allow the intended operation to be performed in a sanitary and wholesome manner. Lighting should not be so excessive as to affect the temperature of the product. (MINOR)

3.3 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary.

3.3.1 Product-contact surfaces.

COMPLIANCE: All product-contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

SERIOUS: A deficiency that has the potential to lead to unsafe product and is highly objectionable.

3.3.2 Other.
COMPLIANCE: All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of any additional equipment or areas of equipment and utensils not referred to in item 3.3.1 above is insufficient and may allow indirect product contamination or adulteration. This can include improper storage of tools or repair materials during maintenance or repair activities.

MINOR: A deficiency that is not likely to reduce a facility's ability to meet acceptable sanitation requirements.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

4. CLEANING AND SANITIZING

REASON:
A sound cleaning and sanitizing operation is vital to facility's food hygiene program. Product contact surfaces are most important and the most obvious. However, improper cleaning of non-product contact surfaces can cause adulteration or contamination to occur through indirect means. Good housekeeping in all areas including employee locker rooms and break rooms is necessary. It also allows the auditor to effectively inspect rooms and areas to determine if they are in fact clean. In addition, the methods used for cleaning and sanitizing shall be such that the product will not be adulterated or contaminated.

4.1 Product contact surfaces not cleaned and sanitized before use.
COMPLIANCE: Product contact surfaces must be cleaned using proper techniques to remove dirt and debris prior to start-up. Sanitizers must be used before any product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered as not being in compliance.

SERIOUS: If product contact surfaces are not cleaned and sanitized effectively.

CRITICAL: If product contact surfaces are not cleaned and sanitized before use.

4.2 Non-product contact surfaces not cleaned before use.
COMPLIANCE: Non-product contact areas must also be cleaned prior to use. This includes walls, ceilings, floors, and other room areas as well as equipment.

MAJOR: If non-product contact surfaces not cleaned.

SERIOUS: If non-product contact surfaces not cleaned before start-up or use.

4.3 Inadequate housekeeping.
COMPLIANCE: Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

MINOR: Excess clutter.

MAJOR: Excess clutter that is highly objectionable.

4.4 Cleaning methods permit adulteration or contamination.
COMPLIANCE: Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance.

SERIOUS: A deficiency that is highly objectionable and could potentially lead to unsafe product.

CRITICAL: A deficiency that has led to unsafe product.

5. PERSONNEL

REASON:
A high degree of personnel compliance is necessary for a sanitation program to work properly. The best systems can easily be defeated if the facility personnel do not maintain high standards in the production and handling of the food product.

5.1 Processing or food handling personnel do not maintain a high degree of personal cleanliness.
COMPLIANCE: All persons, while in food preparation or handling areas, shall wear clean outer garments, use clean cloths, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.

MAJOR: A deficiency that may inhibit the maintenance of food safety.

SERIOUS: A deficiency that has the potential to lead to unsafe product.

5.2 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.
COMPLIANCE: All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated.

2. Remove all unsecured or loose jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

3. If gloves, aprons or arm guards are used in food handling, maintain them in an intact, clean, and sanitary condition. Such items shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If these items are used, they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.

4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.

5. Not expectorate, store clothing or other personal belongings, eat food, drink beverages, or use tobacco in any form, in areas: where food or food ingredients are exposed, used for food processing or storage, or where washing of equipment and utensils is performed.

6. Take other necessary precautions to prevent (1) contamination of foods with microorganisms or foreign substances including, but not limited to: perspiration, hair, cosmetics, tobacco, chemicals, and medications; and (2) misuse of equipment or actions by workers that can cause cross-contamination to occur.

SERIOUS: An employee with potential to cause food contamination.

CRITICAL: An action that has definitely caused food contamination.

5.3 Controls.

5.3.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product. COMPLIANCE: No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological

contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management will make effective effort to notice personnel that exhibit illness and shall require employees to report illness or injury to supervisors. (SERIOUS)

5.3.2 Hand/foot washing and hand/foot sanitizing stations not present or conveniently located.
COMPLIANCE: Hand/foot washing and hand/foot sanitizing stations must be present, functional with adequate supply/concentration of washing and sanitizing agent(s), located conveniently, and in sufficient numbers to provide employees with ease of use.

SERIOUS: If the deficiency has the potential to lead to unsafe product.

CRITICAL: If the deficiency has led to unsafe product.

6. RESTROOMS

REASON:
Sufficient restroom facilities and restroom supplies not only provide for the comfort of employees, but are necessary for good, healthy, and wholesome conditions for the production of food.

6.1 Insufficient number of functional toilets.
COMPLIANCE: The facility must have one operable, conveniently accessible toilet in good repair, per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required. (MINOR)

6.2 Inadequate supplies.
COMPLIANCE: The restrooms must provide supplies such as toilet paper, soap, adequate water supply etc., to meet the employee's needs. (SERIOUS)

6.3 Inadequate Housekeeping.
COMPLIANCE: The restroom facilities must be cleaned to provide for good, healthy, and wholesome conditions for the production of food.

SERIOUS: Restroom facilities not cleaned effectively.

CRITICAL: Restroom conditions exist that has lead to an unsafe product, etc., such as overflowing toilets, or human waste on floors.

7. WATER SUPPLY

REASON:
Process water must be of very high quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or backflow from a contaminated source to the supply system or open vessels of water.

7.1 Unsafe water supply.

COMPLIANCE: The water supply, including well water, will be in compliance when, by certification or direct testing of the supply, it is found to meet the federal standards set forth by the Environmental Protection Agency. Certification of municipal or community systems should be secured at a minimum of once per year. Private supply systems shall have testing performed a minimum of every six (6) months. (CRITICAL)

7.2 Inadequate protection against backflow, back-siphonage, or other sources of contamination.

COMPLIANCE: A facility will be in compliance when all cross-connections are eliminated and when backflow prevention devices are installed wherever backflow or siphonage may occur or where other possible forms of contamination may be present. (SERIOUS)

7.3 Inadequate supply of hot water.

COMPLIANCE: Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a lukewarm supply of water is present in sufficient quantities to perform the necessary task, the plant is in compliance.

MINOR: Supply of hot water is not easily accessible for its proper use.

MAJOR: Inadequate supply of hot water in sufficient quantities to perform the necessary tasks.

8. ICE

REASON:
Ice should be made from safe, potable water, and be handled in the same manner as a food product.

8.1 Not manufactured, handled, or used in a sanitary manner.

COMPLIANCE: A facility will be in compliance when potable water is used for manufacturing ice, when the manufacturing equipment is clean, and the ice only touches impervious surfaces; when the ice holding containers are clean and made of appropriate impervious material; when handling equipment is clean and appropriate for food contact; and when ice is not reused on ready-to-eat product. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice manufactured by outside suppliers.

SERIOUS: If the ice is not manufactured, handled, or used in a sanitary manner and doesn't come in contact with the product. Potability certificate not on file or over 6 months old for ice manufactured by an outside supplier.

CRITICAL: If the ice is not manufactured, handled, or used in a sanitary manner and comes in contact with the product.

9. CHEMICALS

REASON:
Plant chemicals include cleaners, sanitizers, rodenticides, insecticides, and machine lubricants, etc. They must be used according to manufacturers' instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

COMPLIANCE: A facility will be in compliance when the chemicals are used according to manufacturers' instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the product, name of the manufacturer, instructions for use, and the appropriate EPA or USDA approval.

9.1 Chemical(s) improperly used or handled.

SERIOUS: Chemicals improperly used or handled but will not result in an unsafe product.

CRITICAL: Chemicals improperly used or handled which lead to an unsafe product. Non-food grade chlorine used to correct free-chlorine levels.

9.2 Chemical(s) improperly labeled.

SERIOUS: Chemicals improperly labeled but will not result in an unsafe product.

CRITICAL: Chemicals improperly labeled which lead to an unsafe product.

9.3 Chemical(s) improperly stored.

Chemical(s) are not stored in designated area and/or the chemical storage area is not secured to prevent unauthorized access. (SERIOUS)

10. VENTILATION

REASON:
The lack of proper ventilation in a facility may cause condensation or foul odors to occur. Both are due to inadequate air exchange in the building. Condensation in a plant environment may cause filth, bacteria, or other contaminants to adulterate food products through drippage on exposed food, processing equipment, or packaging material. Foul odors normally reveal the presence of bacterial activity within the plant.

10.1 Condensation.

10.1.1 Areas directly affecting product and/or food contact surfaces and/or primary packaging material.

COMPLIANCE: If any condensation is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material or food contact surfaces, the facility is in non-compliance.

SERIOUS: Area is highly objectionable but does not lead to an unsafe product.
CRITICAL: Area has led to an unsafe product.

10.1.2 For nonfood contact areas. (MAJOR)

10.2 Adequate air exchange does not exist.

COMPLIANCE: A facility is in compliance when adequate air exchange exists to preclude the development of foul odors. (MINOR)

11. WASTE DISPOSAL

REASON:
In a manufacturing environment raw material is either utilized in the product or discarded as waste which may be eliminated via the sewerage system or physically removed. Sewerage should be regarded as anything that enters the sewage system including bodily wastes, process water, etc. Any failure to properly eliminate these wastes allows fecal and other human disease organisms to possibly contaminate the food product through splash, foot traffic, or other means. Processing waste is likely to carry filth, decompose quickly, and be an attractant to rodents, insects, and other vermin.

11.1 Improper disposal of:

11.1.1 Sewage.

COMPLIANCE: A facility (including restrooms) is in compliance when sewerage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewerage system.

SERIOUS: System is highly objectionable and has the potential to lead to an unsafe product. Example: System does not drain properly.

CRITICAL: Systems that led to an unsafe product. Example: System overflows, is clogged or backs up into the facility, causing contamination of the product or conditions where contamination is not precluded.

11.1.2 Processing waste.

COMPLIANCE: A facility is in compliance with regard to processing wastes when personnel place the waste in proper containers, placed at appropriate locations throughout the plant, and the waste is removed frequently. (SERIOUS)

Appendix C

References

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Food and Drug Administration *Guidance for Industry Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables October 1998*

Food and Drug Administration *Analysis and Evaluation of Preventative Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce September 2001*

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